MAY - 3 2000

K000681

510(k)
AU5 and AU6 Ultrasound Imaging Systems
Biosound Esaote

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
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Contact Person: Colleen Hittle

Date: January 14, 2000

807.92(a)(2)

Trade Name:	AU5 Ultrasound Imaging System (Addition of 3D Imaging Mode)	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed doppler imaging system	892.1550
Classification Number:	90IYN 90IYO	

807.92(a)(3)

Predicate Device(s)

Esaote	AU5	K980468
Esaote	AU6	K990360

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

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510(k)
AU5 and AU6 Ultrasound Imaging Systems
Biosound Esaote

807.92(a)(5)

Intended Use(s)

The AU5 and AU6 ultrasound imaging systems are intended to be used by a physician for diagnostic imaging in cardiac, abdominal, peripheral vessel and fetal applications.

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510(k) Summary
AU5 and AU6 Ultrasound Imaging Systems
Biosound Esaote

Comparison Chart for Substantial Equivalence

General Characteristics	Esaote AU5 K980468 (predicate)	Esaote AU5 (New mode)
Transducer Type	Annular Array	
	Mechanical Sector	
	Linear	
	Convex	Convex
	Phased Array	
2D Freq MHz	2.5/15	3.5/7.0
PW Freq MHz	2.25/10	2.5/3.8
CW Freq MHz	2.25/5.0	
Imaging Modes	Real-time/2D	Real-time/2D
	M Mode	
	PW Doppler	
	CW Doppler	
	CFM Doppler	
	Power Doppler	
		TEI
Probes MHz		
Annular array	2.5, 3.5, 7.5, 10, 13	
Mechanical Sector	13	
Linear	3.5-7.5	
Convex	3.5-5.0	3.5-7.0
Multifrequency probes	Yes	Yes
Special probes	IVT transvaginal	
	TRT transrectal	
Biopsy attachments	Linear Array	
	Convex	
Monitor size (inches)	14	12
Programmability	6 presets	6 presets
Pulsed/CW Doppler	Yes	Yes
HIPRF	No	No
2D Updating	Yes	Yes
CW steerable	Yes	Yes
Audio stereo	Yes	Yes
Color doppler upgrade	Yes	Yes
ECG	Option	Option
Computer interface	Centronics output	Centronics output
DSM (Dicom strg module)	Yes	No
External size-width	540mm	540mm
-height	540mm	540mm
-depth	690mm	690mm

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510(k) Summary
AU5 and AU6 Ultrasound Imaging Systems
Biosound Esaote

Comparison Chart for Substantial Equivalence

General Characteristics	Esaote AU6 (K#990360)	Esaote AU6 (new mode)
Transducer Type	Annular Array	
	Mechanical Sector	
	Linear	
	Convex	Convex
	Phased Array	
2D Freq MHz	2.5/15	2.5/7.0
PW Freq MHz	2.25/10	2.8/3.6
CW Freq MHz	2.25/5.0	
1.5 D		
Imaging Modes	Real-time/2D	Real-time/2D
	M Mode	
	PW Doppler	
	CW Doppler	
	CFM Doppler	
	Power Doppler	
	Triplex	
		TEI
Probes MHz		
Annular Array	10-20	
Linear	5.0-13	
Convex	3.5-7.5	2.5-7.0
Phased Array	2.5-3.5	
1.5 D	NO	
Multifreqency probes	Yes	Yes
Special probes	IVT transvaginal	
	TRT transrectal	
	LP laparoscopic	
	IOE intraoperative	
Biopsy attachments	Convex	
	Linear	
Monitor size (inches)	14	15
Programmability	6 presets	10 presets
Pulsed/CW Doppler	Yes	Yes
HIPRF	No	Yes
2D Updating	Yes	Yes
CW steerable	Yes	Yes
Audio stereo	Yes	Yes
Color Doppler upgrade	Yes	Yes
ECG	Option	Option
Interconnectivity	NO	YES
DSM integrated	YES	YES
Computer interface	Centronics output	Centronics output
External Size-width	540 mm	580 mm
-height	540 mm	1440 mm
-depth	690 mm	1100 mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2000

Colleen Hittle
Official Correspondent
Biosound Esaote, Inc.
8000 Castleway Drive
Indianapolis, IN 46250

Re: K000681
Trade Name: AU5 and AU6 Ultrasound Imaging Systems with Tissue Harmonic Imaging
Regulatory Class: II
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX
Dated: February 21, 2000
Received: February 28, 2000

Dear Ms. Hittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducer intended for use with the AU5 and AU6 Ultrasound Imaging Systems, as described in your premarket notification:

Transducer Model Number

CA621

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

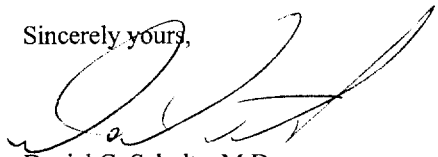
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,



Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

K000681

AU5 System

Appendix F

Diagnostic Ultrasound Indications for Use Form
Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify) TEI
Ophthalmic										
Fetal		P	P	P		P	P		See additional comments	N
Abdominal		P	P	P		P	P		See additional comments	N
Intraoperative (specify) Abdominal		P	P	P		P	P		See additional comments	N
Intraoperative										
Pediatric		P	P	P		P	P		See additional comments	N
Small Organ (specify)		P	P	P		P	P		See additional comments	N
Neonatal Cephalic		P	P	P		P	P		See additional comments	N
Adult Cephalic		P	P	P	P	P	P		See additional comments	N
Cardiac		P	P	P	P	P	P		See additional comments	N
Tranesophageal										
Transrectal		P	P	P		P	P		See additional comments	N
Transvaginal		P	P	P		P	P		See additional comments	N
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		See additional comments	N
Laparoscopic		P	P	P		P	P		See additional comments	N
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically: thyroid, testicles, and breast); PV to include vein mapping
Applicable combined modes: B+PW+CFM+M+PD

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000681

K000681

AU6 System

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify) Tissue Harmonic Imaging
Ophthalmic										
Fetal		P	P	P		P	P		See comments	N
Abdominal		P	P	P	P	P	P		See comments	N
Intraoperative (specify) Abdominal		P	P	P		P	P		See comments	N
Intraoperative (specify) Peripheral vascular		P	P	P		P	P		See comments	N
Intraoperative Neurological										
Pediatric		E	E	E		E	E		See comments	N
Small Organ (specify)		P	P	P		P	P		See comments	N
Neonatal Cephalic		P	P	P		P	P		See comments	N
Adult Cephalic		P	P	P	P	P	P		See Comments	N
Cardiac		P	P	P	P	P	P		See Comments	N
Tranesophageal		P	P	P	P	P	P		See Comments	N
Transrectal		P	P	P		P	P		See Comments	N
Transvaginal		P	P	P		P	P		See Comments	N
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		See comments	N
Laparoscopic		P	P	P		P	P		See Comments	N
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other - Urological		P	P	P		P	P		See Comments	N

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small organs (specifically, thyroid, testicles and breast); Peripheral Vascular to include Vein Mapping & Sclerotherapy

Applicable combined modes: B+PW+CFM+M+PD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K000681

K000681

AU5 and AU6
CA621

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler (CFM)	Amplitude Doppler (PW)	Color Velocity Imaging	Combined (specify)	Other (specify) TEI
Ophthalmic										
Fetal		**E**	**E**	**E**		**E**	**E**		**B+PW+ CFM+M+ PD**	
Abdominal		**E**	**E**	**E**		**E**	**E**		**B+PW+ CFM+M+ PD**	N
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		**E**	**E**	**E**		**E**	**E**		**B+PW+ CFM+M+ PD**	N
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		**E**	**E**	**E**		**E**	**E**		**B+PW+ CFM+M+ PD**	N
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: TEI = Tissue Enhancement Imaging

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

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Concurrence of CDRH, Office of Device Evaluation (ODE) 510(k) Number K000681